

## EC DECLARATION OF CONFORMITY FOR NON-STERILE SUCTION CONNECTING TUBES

<b>Legal Name:</b>	IVOR SHAW LIMITED
<b>Trade Name:</b>	Pennine Healthcare
<b>Manufacturer SRN:</b>	GB-MF-000004160
<b>Business Address:</b>	300 City Gate London Road Derby DE24 8WY United Kingdom
<b>EU Authorised Representative (AR):</b>	Advena Ltd. Tower Business Centre, 2 <sup>nd</sup> Floor, Tower Street, Swatar, BKR 4013, Malta
<b>EU AR SRN:</b>	GB-MF-000000234
<b>Product Name:</b>	Non-Sterile Suction Connecting Tube
<b>Product Codes:</b>	Refer to Appendix 2.
<b>Device Classification:</b>	Class I (Non-Sterile), Rule 1 according to Annex VIII, MDR (EU) 2017/745
<b>Common Specifications:</b>	N/A
<b>Intended use:</b>	A length of flexible single use, non-invasive PVC tubing, intended to interface between suction source and suction devices during a medical/surgical procedure removing fluids, gasses, and debris. To be used on all patient populations by clinicians or trained homecare user, in clinical, homecare and emergency settings.
<b>Basic UDI-DI:</b>	5033241NSCONNECTINGTUBEHK
<b>Notified Body:</b>	N/A
<b>With the Notified Body Number:</b>	N/A
<b>Notified Body Certificate Number:</b>	N/A
<b>Conformity Assessment Route:</b>	Annex II and Annex III of EU MDR 2017/745
<b>GMDN:</b>	A length of flexible non-invasive tube, typically made of synthetic polymer material(s), intended to interface between suction and/or irrigation devices (e.g., catheters, pumps, collection bottles) during a medical/surgical procedure. The tubing may be provided in rolls from which required lengths are cut or may be provided in predetermined lengths with connectors; it does not include additional associated items such as a clamp, spike, or bag (i.e., not a tubing set). This is a single-use device – 16779.

We hereby declare that the medical devices listed above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration of conformity is issued under the sole responsibility of Ivor Shaw Limited trading as Pennine Healthcare.

Signed By:

Date: 05/July/2021

*M. Arun*

Name: **Arun Mahendran**

Position: **Head of Regulatory Affairs**

Place: Derby, United Kingdom

On behalf of IVOR SHAW LTD t/a Pennine Healthcare, Derby, United Kingdom.

**Appendix 1 Applicable Standards:**

Standard/Document Name	Description
ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes
ISO 14971:2019	Medical devices. Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness by particle concentration
ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
BS ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 62366-1:2015	Medical Devices—Part 1: Application of usability engineering to medical devices
BS EN ISO 10079-3:2014	Medical Suction Equipment Part 3: Suction equipment powered from a vacuum or positive pressure gas source
BS EN ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications. General requirements
ASTM D4196-16	Standard Practice for Performance Testing of Shipping Containers and Systems.

**Appendix 2 Product List:**

Product Code	Description
<b>CCT-4142/BULK*</b>	Suction Connecting Tube Conductive 6mm x 2.7m F/F Bulk
<b>CCT-4172/BULK*</b>	Suction Connecting Tube Conductive 6mm x 3.5m F/F Bulk
<b>CCT-4743/BULK*</b>	Suction Connecting Tube Link Conductive 7mm x 2.7m F/F Bulk
<b>CCT-4782/BULK*</b>	Suction Connecting Tube Link Conductive 7mm x 3.7m F/M Bulk
<b>CCT-4783/BULK*</b>	Suction Connecting Tube Link Conductive 7mm x 3.7m F/F Bulk
<b>CT-4012/BULK*</b>	Suction Connecting Tube 6mm x 1.8m F/F Bulk
<b>CT-4012/NS*</b>	Suction Connecting Tube 6mm x 1.8m F/F Bulk
<b>CT-4014/NS*</b>	Suction Connecting Tube 6mm x 1.8m F/F/M Bulk
<b>CT-4020/BULK*</b>	Suction Connecting Tube 6mm x 2mt F/Flush cut end Bulk
<b>CT-4022/BULK*</b>	Suction Connecting Tube 6mm x 2m F/F Bulk
<b>CT-4024/BULK*</b>	Suction Connecting Tube 6mm x 2m F/F/M Bulk
<b>CT-4030/BULK*</b>	Suction Connecting Tube 6mm x 3m F/Flush cut end Bulk
<b>CT-4031/W/BULK*</b>	Suction Connecting Tube 6mm x 3m M/F Bulk
<b>CT-4032/BULK*</b>	Suction Connecting Tube 6mm x 3m F/F Bulk
<b>CT-4034/BULK*</b>	Suction Connecting Tube 6mm x 3m F/F/M Bulk
<b>CT-4034/NS*</b>	Suction Connecting Tube 6mm x 3m F/F/M Bulk
<b>CT-4034/VC/BULK*</b>	Suction Connecting Tube 6mm x 3m F/F/M VC Bulk
<b>CT-4042/BULK*</b>	Suction Connecting Tube 6mm x 2.7m F/F Bulk
<b>CT-4042/SD/BULK*</b>	Suction Connecting Tube 6mm x 2.7m F/F Bulk
<b>CT-4044/BULK*</b>	Suction Connecting Tube 6mm x 2.7m F/F/M Bulk
<b>CT-4062/BULK*</b>	Suction Connecting Tube 6mm x 6m F/F Bulk
<b>CT-4072/BULK*</b>	Suction Connecting Tube 6mm x 3.5m F/F Bulk

<b>CT-4074/BULK*</b>	Suction Connecting Tube 6mm x 3.5m F/F/M Bulk
<b>CT-4082/BULK*</b>	Suction Connecting Tube 6mm x 1m F/F Bulk
<b>CT-4092/BULK*</b>	Suction Connecting Tube 6mm x 4m F/F Bulk
<b>CT-4094/BULK*</b>	Suction Connecting Tube 6mm x 4m F/F/M Bulk
<b>CT-4312/BULK*</b>	Suction Connecting Tube 5mm x 1.8m F/F Bulk
<b>CT-4313/NS*</b>	Suction Connecting Tube 5mm x 1.5m F/M VC
<b>CT-4315/BULK*</b>	Suction Connecting Tube 5mm x 1.8m F/M Bulk
<b>CT-4316/BULK*</b>	Suction Connecting Tube 5mm x 1.8m F/M VC Bulk
<b>CT-4324/VC/BULK*</b>	Suction Connecting Tube 5mm x 2m F/F/M Bulk
<b>CT-4332/BULK*</b>	Suction Connecting Tube 5mm x 3m F/F Bulk
<b>CT-4334/NS*</b>	Suction Connecting Tube 5mm x 3m F/F/M Bulk
<b>CT-4372/BULK*</b>	Suction Connecting Tube 5mm x 3.5m F/F Bulk
<b>CT-4374/BULK*</b>	Suction Connecting Tube 5mm x 3.5m F/F/M Bulk
<b>CT-4622/BULK*</b>	Suction Connecting Tube 8mm x 2m F/F Bulk
<b>CT-4630/BULK*</b>	Suction Connecting Tube 8mm x 3m F/Flush cut end Bulk
<b>CT-4632/BULK*</b>	Suction Connecting Tube 8mm x 3m F/F Bulk
<b>CT-4642/BULK*</b>	Suction Connecting Tube 8mm x 4m F/F Bulk
<b>CT-4662/BULK*</b>	Suction Connecting Tube 8mm x 6m F/F Bulk
<b>CT-4713/BULK*</b>	Suction Connecting Tube Link 7mm x 1.8m F/F Bulk
<b>CT-4722/BULK*</b>	Suction Connecting Tube Flexi Rib 7mm x 2m F/F Bulk
<b>CT-4724/BULK*</b>	Suction Connecting Tube Flexi Rib 7mm x 2m F/F/M Bulk
<b>CT-4732/BULK*</b>	Suction Connecting Tube Flexi Rib 7mm x 3m F/F Bulk
<b>CT-4734/BULK*</b>	Suction Connecting Tube Flexi Rib 7mm x 3m F/F/M Bulk
<b>CT-4741/VC/BULK*</b>	Suction Connecting Tube Flexi Rib VC 7mm x 2.5m F/F/M Bulk
<b>CT-4743/BULK*</b>	Suction Connecting Tube Link 7mm x 2.7m F/F Bulk
<b>CT-4772/BULK*</b>	Suction Connecting Tube Flexi Rib 7mm x 3.5m F/F
<b>CT-4781/BULK*</b>	Suction Connecting Tube Link 7mm x 3.7m F/M
<b>CT-4783/BULK*</b>	Suction Connecting Tube Link 7mm x 3.7m F/F
<b>CT-4792/BULK*</b>	Suction Connecting Tube Flexi Rib 7mm x 4m F/F Bulk
<b>CT-4922/BULK*</b>	Suction Connecting Tube Flexi Rib 6mm x 2m F/F Bulk
<b>CT-4932/BULK*</b>	Suction Connecting Tube Flexi Rib 6mm x 3m F/F Bulk
<b>CT-4934/BULK*</b>	Suction Connecting Tube Flexi Rib 6mm x 3m F/F/M Bulk
<b>CT-4936/BULK*</b>	Suction Connecting Tube Flexi Rib 6mm x 3m F/F
<b>CT-4972/BULK*</b>	Suction Connecting Tube Flexi Rib 6mm x 3.5m F/F
<b>CTS-4027/BULK*</b>	Suction Connecting Tube Soft 6mm x 2m F/F/M Bulk
<b>CTS-4032/BULK*</b>	Suction Connecting Tube Soft 6mm x 3m F/F Bulk
<b>CTS-4062/BULK*</b>	Suction Connecting Tube Soft 6mm x 6m F/F Bulk
<b>CTS-4072/BULK*</b>	Suction Connecting Tube Soft 6mm x 3.5m F/F Bulk
<b>CTS-4092/BULK*</b>	Suction Connecting Tube Soft 6mm x 4m F/F Bulk
<b>CTS-4322/NS*</b>	Suction Connecting Tube Soft 5mm x 2m F/F Bulk
<b>CTS-4332/BULK*</b>	Suction Connecting Tube Soft 5mm x 3m F/F Bulk
<b>CTS-4632/BULK*</b>	Suction Connecting Tube Soft 8mm x 3m F/F Bulk
<b>CTS-4640/R/BULK*</b>	Suction Connecting Tube Soft 8mm x 4m F/Flush cut end Bulk
<b>CTS-4642/BULK*</b>	Suction Connecting Tube Soft 8mm x 4m F/F Bulk

<b>DP-501/BULK*</b>	Straight Rigid Connector Bulk
<b>VC-2/100/BULK*</b>	Vacuum control unit (bulk NS)
<b>VC-2/BULK*</b>	Vacuum control unit (bulk NS)
<b>CTS30/10/BULK*</b>	Suction Connecting Tube 30mm x 10m (No Connectors) Bulk

\* Added to procedure pack or supplied as non-sterile to Procedure Pack/Kit makers

## Non-Sterile

<b>Product Code</b>	<b>Description</b>
<b>SL-8005</b>	Link Bubble Tubing Plain 5mm x 30m
<b>SL-8007</b>	Link Bubble Tubing Plain 7mm x 30m
<b>SL-8055</b>	Link Bubble Tubing Plain 5mm x 50m
<b>SL-8205</b>	Link Bubble Tubing Conductive 5mm x 30m
<b>SL-8207</b>	Link Bubble Tubing Conductive 7mm x 30m
<b>SL-8255</b>	Link Bubble Tubing Conductive 5mm x 50m
<b>SL-8256</b>	Link Bubble Tubing Conductive 6mm x 50m
<b>SL-8307</b>	Link Bubble Tubing Plain 7mm x 30m
<b>SL-8356</b>	Link Bubble Tubing Plain 6mm x 49.98m